



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Food and Drug Administration  
Nashville District Office

OK  
3/10/99  
M2447N

297 Plus Park Boulevard  
Nashville, TN 37217

March 9, 1999

**CERTIFIED-RETURN RECEIPT REQUESTED**

LifeSouth Community Blood Centers  
1221 N.W. 13th Street  
Gainesville, FL 32601

Attn: Nancy Eckert  
President & CEO

**WARNING LETTER NO. 99 NSV 08**

Dear Ms. Eckert:

During an inspection of LifeSouth Community Blood Centers, d/b/a Montgomery Community Blood Bank, 1601 Eastern Boulevard, Montgomery, Alabama on November 9 - 11, 16 - 25, and December 2 - 3, 1998, our investigator documented violations of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act and Title 21, Code of Federal Regulations, Parts 600 to 680, as follows:

- Failure to maintain concurrent, detailed and/or accurate records [21 CFR 600.12(a), and 606.160(a)];
- Failure to follow your standard operating procedures relevant to the review of single donor record forms prior to labeling and distribution of units of blood and/or blood products [21 CFR 606.100(c)].

The above noted violations are not intended to serve as an all-inclusive list of deficiencies noted at your Montgomery facility. It remains your responsibility as the Responsible Official to assure that your establishment is in compliance with all requirements of the federal regulations.

We acknowledge receipt of your December 18, 1998, response to the FDA Form 483 issued to Montgomery Community Blood Bank at the termination of our inspection. However, the fact that a number of the deviations noted during our inspection continued over a period of several months is of primary concern to us. As noted in your response, many of the repeated deficiencies listed on the

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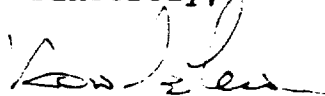
FDA Form 483 had been documented by the firm on its "Reportable Event Forms;" the failure to promptly and effectively address the noted deficiencies is indicative of lax supervision and/or a need for further training of the personnel involved. In any case, only a future re-inspection can determine the adequacy and permanence of your stated changes and corrections.

In response to your inquiry concerning the need to maintain manual discard records when the same date is computerized, I can assure you that duplicative, manual records are not required, PROVIDED your computer system(s) are validated to ensure that all necessary data is entered, that the stored data is safely backed-up in the event of a system failure, and that you can make hard copies of the data available for FDA review upon request.

If you care to respond further to any of these matters, please do so to the attention of Frank J. Jancarek, Compliance Officer, at the above letterhead address.

If you fail to promptly and effectively correct the deficiencies noted at this facility, it could result in regulatory action without further notice. Such action includes license suspension and/or revocation, seizure and/or injunction.

Sincerely,



Howard E. Lewis  
Director, Field Operations Branch

HEL/kl

cc: Judy R. Russell  
Branch Director  
Montgomery Community Blood Bank  
1601 Eastern Boulevard  
Montgomery, AL 36117